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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,362	06/25/2005	Cosimo De Bari	50304/030001	8489

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CLARK & ELBING LLP  
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BOSTON, MA 02110

EXAMINER
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SINGH, ANOOP KUMAR

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/522,362	<b>Applicant(s)</b> DE BARI ET AL.	
	<b>Examiner</b> Anoop Singh	<b>Art Unit</b> 1632	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 36-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1 and 36-53 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### DETAILED ACTION

1. Claims 1, 36-53 are under consideration.

#### ***Election/Restrictions***

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1, 36-42 and 53, drawn to a composition comprising a population of mammalian muscle progenitor cells derived from joint tissue.

Group II, claims 43-49, drawn to a method for repairing or preventing muscle dysfunction in a patient by administering the pharmaceutical composition comprising a population of mammalian muscle progenitor cells.

Group III, claims 50-52, drawn to a method of selecting muscle precursor cells comprising contacting a joint derived cell population with antibody or a ligand for a receptor.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The inventions listed as Groups I do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking the inventions of groups I-III is a composition comprising a population of mammalian muscle progenitor cells derived from joint tissue. De Bari et al., (Arthritis Rheum., 2001, 44(8), 1928-1942; IDS) disclose and characterize a mesenchymal stem cell from human synovial membrane. De Bari et al teach synovial membrane derived cells can be expanded up to 10 passages and can be induced into multi lineage differentiation (pp 1929, column 1, 3<sup>rd</sup> paragraph; column 2, 2<sup>nd</sup> paragraph). De Bari et al (Oncology Research 12 (6-7), 2001 Millennium International conference of molecular and Tumor Biology, Greece, September 6-7, 2001; IDS) disclose identification and characterization of multipotent MSC from human synovial membrane. De Bari et al further teach myogenic potential of human synovial membrane derived MS cells *in vivo*. The expression of c-met or any other cell maker will be an inherent property of the cell.

Therefore, the instant technical feature of Groups I-III does not contribute over prior art.

The technical feature of group I is a composition comprising population of mammalian muscle progenitor cells. The invention of Group II is directed to therapy, while group III is drawn to selecting cells by antibody or ligand receptor, which do not share same inventive concept as in group I. The claimed invention of group II recite therapy, while group III require antibody or receptor ligand, which are neither required nor recited in the claimed invention of group I, and thus have their own technical feature e.g. cell composition (group I), cell therapy (group II), and screening cells by antibody (group III).

Inventions of the groups II-III are patentably distinct each from the other because they are drawn to methods that have distinct steps and use material compositions that have distinct structure, function and utility. For example, the method step of group II require muscle progenitor cells for repairing muscle dysfunction, while the method step of group III require selecting muscle progenitor cells by contacting cell with a binding agent such as antibody. These are distinct and different method steps and therefore, searching for two distinct method steps will not be coextensive and will require separate and independent searches in the patent and non-patent literature.

The composition of the group I is patentably distinct each from the methods of groups II-III because methods cannot be used to produce the compositions. Alternatively, the compositions may not be used in methods or will be used in more than one method.

Each invention is directed to distinct goal, which comprises the use of progenitor cell composition in order to achieve its respective and intended objective. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons set forth above.

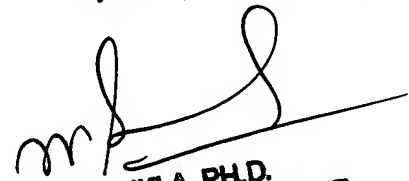
4. A search and examination of more than one invention as defined above would unduly burden the office. Each of the inventions requires a different search of the art and concerns separate considerations of patentability. For example, the subject matter of many of the subject matter of many of the inventions is not largely co-extensive as the inventions are related to distinct method and compositions. Therefore, restriction as defined above is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anoop Singh whose telephone number is (571) 272-3306. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272- 0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Anoop Singh, Ph.D.  
Examiner, AU 1632



**RAM R. SHUKLA, PH.D.**  
**SUPERVISORY PATENT EXAMINER**